

AMENDED IN ASSEMBLY JUNE 26, 2013

AMENDED IN SENATE MAY 28, 2013

AMENDED IN SENATE MAY 24, 2013

AMENDED IN SENATE MAY 14, 2013

AMENDED IN SENATE MAY 1, 2013

SENATE BILL

No. 809

Introduced by Senators DeSaulnier and Steinberg
(Coauthors: Senators Hancock, Lieu, Pavley, and Price)
(Coauthor: Assembly Member Blumenfield)

February 22, 2013

An act to add Sections 805.8 and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section 11165.4 to, the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 809, as amended, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule

II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would require the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine to charge practitioners under their supervision who are authorized to prescribe, order, administer, furnish, or dispense controlled substances a fee of up to 1.16% of the renewal fee that the licensee was subject to as of July 1, 2013, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. This bill would also require the California State Board of Pharmacy to charge wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers under their supervision a fee of up to 1.16% of the renewal fee that the wholesaler, nonresident wholesaler, or veterinary food-animal drug retailer was subject to as of July 1, 2013, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. The bill would require each of these fees to be due and payable at the time the license is renewed and require the fee to be submitted with the renewal fee. The bill would also permit specified insurers, health care service plans, and qualified manufacturers, to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California.

This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to be strongly encouraged to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances. The bill would make other related and conforming changes.

(4) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) The Controlled Substance Utilization Review and Evaluation
- 4 System (CURES) is a valuable preventive, investigative, and
- 5 educational tool for health care providers, regulatory boards,
- 6 educational researchers, and law enforcement. Recent budget cuts
- 7 to the Attorney General's Division of Law Enforcement have
- 8 resulted in insufficient funding to support the CURES Prescription
- 9 Drug Monitoring Program (PDMP). The PDMP is necessary to
- 10 ensure health care professionals have the necessary data to make
- 11 informed treatment decisions and to allow law enforcement to
- 12 investigate diversion of prescription drugs. Without a dedicated
- 13 funding source, the CURES PDMP is not sustainable.
- 14 (b) Each year CURES responds to more than 800,000 requests
- 15 from practitioners and pharmacists regarding all of the following:

1 (1) Helping identify and deter drug abuse and diversion of
2 prescription drugs through accurate and rapid tracking of Schedule
3 II, Schedule III, and Schedule IV controlled substances.

4 (2) Helping practitioners make better prescribing decisions.

5 (3) Helping reduce misuse, abuse, and trafficking of those drugs.

6 (c) Schedule II, Schedule III, and Schedule IV controlled
7 substances have had deleterious effects on private and public
8 interests, including the misuse, abuse, and trafficking in dangerous
9 prescription medications resulting in injury and death. It is the
10 intent of the Legislature to work with stakeholders to fully fund
11 the operation of CURES which seeks to mitigate those deleterious
12 effects and serve as a tool for ensuring safe patient care, and which
13 has proven to be a cost-effective tool to help reduce the misuse,
14 abuse, and trafficking of those drugs.

15 (d) The following goals are critical to increase the effectiveness
16 and functionality of CURES:

17 (1) Upgrading the PDMP so that it is capable of accepting
18 real-time updates and is accessible in real-time, 24 hours a day,
19 seven days a week.

20 (2) Upgrading all prescription drug monitoring programs in
21 California so that they are capable of operating in conjunction with
22 all national prescription drug monitoring programs.

23 (3) Providing subscribers to prescription drug monitoring
24 programs access to information relating to controlled substances
25 dispensed in California, including those dispensed through the
26 ~~federal~~ *United States* Department of ~~Veterans~~² *Veterans* Affairs,
27 the Indian Health Service, the Department of Defense, and any
28 other entity with authority to dispense controlled substances in
29 California.

30 (4) Upgrading the PDMP so that it is capable of accepting
31 electronic prescriptions, thereby enabling more reliable, complete,
32 and timely prescription monitoring.

33 SEC. 2. Section 805.8 is added to the Business and Professions
34 Code, to read:

35 805.8. (a) (1) In addition to the fees charged for licensure,
36 certification, and renewal, at the time those fees are charged, the
37 Medical Board of California, the Dental Board of California, the
38 California State Board of Pharmacy, the Veterinary Medical Board,
39 the Board of Registered Nursing, the Physician Assistant
40 Committee of the Medical Board of California, the Osteopathic

1 Medical Board of California, the Naturopathic Medicine Committee
2 of the Osteopathic Medical Board of California, the State Board
3 of Optometry, and the California Board of Podiatric Medicine shall
4 charge each licensee authorized pursuant to Section 11150 of the
5 Health and Safety Code to prescribe, order, administer, furnish,
6 or dispense Schedule II, Schedule III, or Schedule IV controlled
7 substances a fee of up to 1.16 percent of the renewal fee that the
8 licensee was subject to as of July 1, 2013, to be assessed annually.
9 This fee shall be due and payable at the time the licensee renews
10 his or her license and shall be submitted with the licensee's renewal
11 fee. In no case shall this fee exceed the reasonable costs associated
12 with operating and maintaining CURES for the purpose of
13 regulating prescribers and dispensers of controlled substances
14 licensed or certificated by these boards.

15 (2) In addition to the fees charged for licensure, certification,
16 and renewal, at the time those fees are charged, the California State
17 Board of Pharmacy shall charge wholesalers and nonresident
18 wholesalers of dangerous drugs, licensed pursuant to Article 11
19 (commencing with Section 4160) of Chapter 9, a fee of up to 1.16
20 percent of the renewal fee that the wholesaler or nonresident
21 wholesaler was subject to as of July 1, 2013, to be assessed
22 annually. This fee shall be due and payable at the time the
23 wholesaler or nonresident wholesaler renews its license and shall
24 be submitted with the wholesaler's or nonresident wholesaler's
25 renewal fee. In no case shall this fee exceed the reasonable costs
26 associated with operating and maintaining CURES for the purpose
27 of regulating wholesalers and nonresident wholesalers of dangerous
28 drugs licensed or certificated by that board.

29 (3) In addition to the fees charged for licensure, certification,
30 and renewal, at the time those fees are charged, the California State
31 Board of Pharmacy shall charge veterinary food-animal drug
32 retailers, licensed pursuant to Article 15 (commencing with Section
33 4196) of Chapter 9, a fee of up to 1.16 percent of the renewal fee
34 that the drug retailer was subject to as of July 1, 2013, to be
35 assessed annually. This fee shall be due and payable at the time
36 the drug retailer renews its license and shall be submitted with the
37 drug retailers' renewal fee. In no case shall this fee exceed the
38 reasonable costs associated with operating and maintaining CURES
39 for the purpose of regulating veterinary food-animal drug retailers
40 licensed or certificated by that board.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for operating and maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. Section 2196.8 is added to the Business and Professions Code, to read:

2196.8. The board shall periodically develop and disseminate information and educational material regarding assessing a patient's risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Care Services and the Department of Justice in developing the materials to be distributed pursuant to this section.

SEC. 4. Section 11164.1 of the Health and Safety Code is amended to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II and Schedule III controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (e) of Section 11165.

1 (b) Pharmacies may dispense prescriptions for Schedule III,
2 Schedule IV, and Schedule V controlled substances from
3 out-of-state prescribers pursuant to Section 4005 of the Business
4 and Professions Code and Section 1717 of Title 16 of the California
5 Code of Regulations.

6 (c) This section shall become operative on January 1, 2005.

7 SEC. 5. Section 11165 of the Health and Safety Code is
8 amended to read:

9 11165. (a) To assist health care practitioners in their efforts
10 to ensure appropriate prescribing, ordering, administering,
11 furnishing, and dispensing of controlled substances, law
12 enforcement and regulatory agencies in their efforts to control the
13 diversion and resultant abuse of Schedule II, Schedule III, and
14 Schedule IV controlled substances, and for statistical analysis,
15 education, and research, the Department of Justice shall, contingent
16 upon the availability of adequate funds in the CURES accounts
17 within the Contingent Fund of the Medical Board of California,
18 the Pharmacy Board Contingent Fund, the State Dentistry Fund,
19 the Board of Registered Nursing Fund, the Naturopathic Doctor's
20 Fund, the Osteopathic Medical Board of California Contingent
21 Fund, the Veterinary Medical Board Contingent Fund, the
22 Optometry Fund, the Board of Podiatric Medicine Fund, and the
23 CURES Fund, maintain the Controlled Substance Utilization
24 Review and Evaluation System (CURES) for the electronic
25 monitoring of, and Internet access to information regarding, the
26 prescribing and dispensing of Schedule II, Schedule III, and
27 Schedule IV controlled substances by all practitioners authorized
28 to prescribe, order, administer, furnish, or dispense these controlled
29 substances.

30 (b) The reporting of Schedule III and Schedule IV controlled
31 substance prescriptions to CURES shall be contingent upon the
32 availability of adequate funds for the Department of Justice for
33 the purpose of funding CURES.

34 (c) The Department of Justice may seek and use grant funds to
35 pay the costs incurred by the operation and maintenance of
36 CURES. The department shall annually report to the Legislature
37 and make available to the public the amount and source of funds
38 it receives for support of CURES. Grant funds shall not be
39 appropriated from the Contingent Fund of the Medical Board of
40 California, the Pharmacy Board Contingent Fund, the State

1 Dentistry Fund, the Board of Registered Nursing Fund, the
2 Naturopathic Doctor's Fund, the Osteopathic Medical Board of
3 California Contingent Fund, the Veterinary Medical Board
4 Contingent Fund, the Optometry Fund, or the Board of Podiatric
5 Medicine Fund, for the purpose of funding CURES.

6 (d) (1) The operation of CURES shall comply with all
7 applicable federal and state privacy and security laws and
8 regulations.

9 (2) *CURES shall operate under existing provisions of law to*
10 *safeguard the privacy and confidentiality of patients. Data obtained*
11 *from CURES shall only be provided to appropriate state, local,*
12 *and federal public agencies for disciplinary, civil, or criminal*
13 *purposes and to other agencies or entities, as determined by the*
14 *Department of Justice, for the purpose of educating practitioners*
15 *and others in lieu of disciplinary, civil, or criminal actions. Data*
16 *may be provided to public or private entities, as approved by the*
17 *Department of Justice, for educational, peer review, statistical, or*
18 *research purposes, provided that patient information, including*
19 *any information that may identify the patient, is not compromised.*
20 *Further, data disclosed to any individual or agency as described*
21 *in this subdivision shall not be disclosed, sold, or transferred to*
22 *any third party. The Department of Justice may establish policies,*
23 *procedures, and regulations regarding the use, access, evaluation,*
24 *management, implementation, operation, storage, and security of*
25 *the information within—CURES. CURES, consistent with this*
26 *subdivision.*

27 (e) For each prescription for a Schedule II, Schedule III, or
28 Schedule IV controlled substance, as defined in the controlled
29 substances schedules in federal law and regulations, specifically
30 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21
31 of the Code of Federal Regulations, the dispensing pharmacy,
32 clinic, or other dispenser shall report the following information to
33 the Department of Justice as soon as reasonably possible, but not
34 more than seven days after the date a controlled substance is
35 dispensed, unless monthly reporting is permitted pursuant to
36 subdivision (f) of Section 11190, and in a format specified by the
37 Department of Justice:

38 (1) Full name, address, and telephone number of the ultimate
39 user or research subject, or contact information as determined by

1 the Secretary of the United States Department of Health and Human
2 Services, and the gender, and date of birth of the ultimate user.

3 (2) The prescriber's category of licensure and license number,
4 the federal controlled substance registration number, and the state
5 medical license number of any prescriber using the federal
6 controlled substance registration number of a government-exempt
7 facility.

8 (3) Pharmacy prescription number, license number, and federal
9 controlled substance registration number.

10 (4) National Drug Code (NDC) number of the controlled
11 substance dispensed.

12 (5) Quantity of the controlled substance dispensed.

13 (6) International Statistical Classification of Diseases, 9th
14 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

15 (7) Number of refills ordered.

16 (8) Whether the drug was dispensed as a refill of a prescription
17 or as a first-time request.

18 (9) Date of origin of the prescription.

19 (10) Date of dispensing of the prescription.

20 (f) The Department of Justice may invite stakeholders to assist,
21 advise, and make recommendations on the establishment of rules
22 and regulations necessary to ensure the proper administration and
23 enforcement of the CURES database. All prescriber invitees shall
24 be licensed by one of the boards or committees identified in
25 subdivision (a) of Section 805.8 of the Business and Professions
26 Code, in active practice in California, and a regular user of CURES.

27 (g) The Department of Justice shall, prior to upgrading CURES,
28 consult with prescribers licensed by one of the boards or
29 committees identified in subdivision (a) of Section 805.8 of the
30 Business and Professions Code, one or more of the regulatory
31 boards or committees identified in subdivision (a) of Section 805.8
32 of the Business and Professions Code, and any other stakeholder
33 identified by the ~~department~~ *department*, for the purpose of
34 identifying desirable capabilities and upgrades to the CURES
35 Prescription Drug Monitoring Program.

36 (h) The Department of Justice may establish a process to educate
37 authorized subscribers of CURES on how to access and use
38 CURES.

39 (i) The CURES Fund is hereby established within the State
40 Treasury. The CURES Fund shall consist of all funds made

1 available to the Department of Justice for the purpose of funding
2 CURES. Money in the CURES Fund shall, upon appropriation by
3 the Legislature, be available for allocation to the Department of
4 Justice for the purpose of funding CURES.

5 SEC. 6. Section 11165.1 of the Health and Safety Code is
6 amended to read:

7 11165.1. (a) (1) A licensed health care practitioner eligible
8 to prescribe Schedule II, Schedule III, or Schedule IV controlled
9 substances or a pharmacist shall submit an application developed
10 by the Department of Justice to obtain approval to access
11 information online regarding the controlled substance history of
12 a patient that is stored on the Internet and maintained within the
13 Department of Justice, and, upon approval, the department shall
14 release to that practitioner or pharmacist the electronic history of
15 controlled substances dispensed to an individual under his or her
16 care based on data contained in the CURES Prescription Drug
17 Monitoring Program (PDMP).

18 (A) An application may be denied, or a subscriber may be
19 suspended, for reasons which include, but are not limited to, the
20 following:

21 (i) Materially falsifying an application for a subscriber.

22 (ii) Failure to maintain effective controls for access to the patient
23 activity report.

24 (iii) Suspended or revoked federal Drug Enforcement
25 Administration (DEA) registration.

26 (iv) Any subscriber who is arrested for a violation of law
27 governing controlled substances or any other law for which the
28 possession or use of a controlled substance is an element of the
29 crime.

30 (v) Any subscriber accessing information for any other reason
31 than caring for his or her patients.

32 (B) Any authorized subscriber shall notify the Department of
33 Justice within 30 days of any changes to the subscriber account.

34 (2) To allow sufficient time for licensed health care practitioners
35 eligible to prescribe Schedule II, Schedule III, or Schedule IV
36 controlled substances and a pharmacist to apply and receive access
37 to PDMP, a written request may be made, until July 1, 2012, and
38 the Department of Justice may release to that practitioner or
39 pharmacist the history of controlled substances dispensed to an
40 individual under his or her care based on data contained in CURES.

1 (b) Any request for, or release of, a controlled substance history
2 pursuant to this section shall be made in accordance with guidelines
3 developed by the Department of Justice.

4 (c) (1) Until the Department of Justice has issued the
5 notification described in paragraph (3), in order to prevent the
6 inappropriate, improper, or illegal use of Schedule II, Schedule
7 III, or Schedule IV controlled substances, the Department of Justice
8 may initiate the referral of the history of controlled substances
9 dispensed to an individual based on data contained in CURES to
10 licensed health care practitioners, pharmacists, or both, providing
11 care or services to the individual.

12 (2) Upon the Department of Justice issuing the notification
13 described in paragraph (3), licensed health care practitioners
14 eligible to prescribe Schedule II, Schedule III, or Schedule IV
15 controlled substances and pharmacists shall be strongly encouraged
16 to access and consult the electronic history of controlled substances
17 dispensed to an individual under his or her care prior to prescribing
18 or dispensing a Schedule II, Schedule III, or Schedule IV controlled
19 substance.

20 (3) The Department of Justice shall notify licensed health care
21 practitioners and pharmacists who have submitted the application
22 required pursuant to subdivision (a) when the department
23 determines that CURES is capable of accommodating all users,
24 but not before June 1, 2015. The department shall provide a copy
25 of the notification to the Secretary of State, the Secretary of the
26 Senate, the Chief Clerk of the Assembly, and the Legislative
27 Counsel, and shall post the notification on the department's Internet
28 Web site.

29 (d) The history of controlled substances dispensed to an
30 individual based on data contained in CURES that is received by
31 a practitioner or pharmacist from the Department of Justice
32 pursuant to this section shall be considered medical information
33 subject to the provisions of the Confidentiality of Medical
34 Information Act contained in Part 2.6 (commencing with Section
35 56) of Division 1 of the Civil Code.

36 (e) Information concerning a patient's controlled substance
37 history provided to a prescriber or pharmacist pursuant to this
38 section shall include prescriptions for controlled substances listed
39 in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code
40 of Federal Regulations.

1 SEC. 7. Section 11165.4 is added to the Health and Safety
2 Code, to read:

3 11165.4. (a) The Department of Justice may seek private funds
4 from insurers, health care service plans, and qualified
5 manufacturers for the purpose of supporting CURES. Insurers,
6 health care service plans, and qualified manufacturers may
7 contribute by submitting their payment to the Controller for deposit
8 into the CURES Fund established pursuant to subdivision (e) of
9 Section 11165. The department shall make information about the
10 amount and the source of all private funds it receives for support
11 of CURES available to the public. Contributions to the CURES
12 Fund pursuant to this subdivision shall be nondeductible for state
13 tax purposes.

14 (b) For purposes of this section, the following definitions apply:

15 (1) “Controlled substance” means a drug, substance, or
16 immediate precursor listed in any schedule in Section 11055,
17 11056, or 11057 of the Health and Safety Code.

18 (2) “Health care service plan” means an entity licensed pursuant
19 to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter
20 2.2 (commencing with Section 1340) of Division 2 of the Health
21 and Safety Code).

22 (3) “Insurer” means an admitted insurer writing health insurance,
23 as defined in Section 106 of the Insurance Code, and an admitted
24 insurer writing workers’ compensation insurance, as defined in
25 Section 109 of the Insurance Code.

26 (4) “Qualified manufacturer” means a manufacturer of a
27 controlled substance, but does not mean a wholesaler or nonresident
28 wholesaler of dangerous drugs, regulated pursuant to Article 11
29 (commencing with Section 4160) of Chapter 9 of Division 2 of
30 the Business and Professions Code, a veterinary food-animal drug
31 retailer, regulated pursuant to Article 15 (commencing with Section
32 4196) of Chapter 9 of Division 2 of the Business and Professions
33 Code, or an individual regulated by the Medical Board of
34 California, the Dental Board of California, the California State
35 Board of Pharmacy, the Veterinary Medical Board, the Board of
36 Registered Nursing, the Physician Assistant Committee of the
37 Medical Board of California, the Osteopathic Medical Board of
38 California, the State Board of Optometry, or the California Board
39 of Podiatric Medicine.

1 SEC. 8. This act is an urgency statute necessary for the
2 immediate preservation of the public peace, health, or safety within
3 the meaning of Article IV of the Constitution and shall go into
4 immediate effect. The facts constituting the necessity are:

5 In order to protect the public from the continuing threat of
6 prescription drug abuse at the earliest possible time, it is necessary
7 that this act take effect immediately.

O